

REMARKS

Claim 1 has been amended to specify a graft composition “consisting essentially of” basement membrane of a warm-blooded vertebrate.

Rejection of Claims 1-16 Under 35 U.S.C. § 103(a) -

The Examiner has rejected claims 1-16 under 35 U.S.C. § 103(a) as being obvious over WO 98/25637 in view of U.S. Patent No. 5,955,110 (hereinafter the ‘110 patent), WO 03/084410, and U.S. Patent No. 4,399,123 (hereinafter the ‘123 patent). The Examiner contends that WO 98/25637 teaches the use of a tissue graft composition comprising liver basement membrane of a warm-blooded vertebrate for repair of damaged or diseased tissues, where the composition is treated to remove cells and cellular components. The Examiner further contends that one skilled in the art would have been motivated to use the invention of WO 98/25637 for the repair of the abdominal wall because the ‘110 patent teaches the use of a multilayered, homolaminate submucosal graft for abdominal wall repair, and WO 03/084410 and the ‘123 patent each teach a method for using basement membrane for the treatment of hernias. Applicant respectfully traverses the Examiner’s rejection. Applicant’s amended claims 1-16 are not obvious over WO 98/25637 in view of the ‘110 patent, WO 03/084410, and the ‘123 patent.

References Cannot Be Combined Where References Teach Away from Their Combination -

It is improper to combine references where the references teach away from their combination. See MPEP § 2145; *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). The ‘123 patent not only teaches away from the claimed invention, but the ‘123 patent also teaches away from combination with WO 98/25637. A skilled artisan

would not combine a reference that teaches that glycoproteins must be removed to create a tissue composition that is suitable for implantation, with a reference that teaches the use of a tissue graft composition comprising liver basement membrane with glycoproteins for the repair of damaged or diseased tissues.

In the present Office Action, the Examiner contends that the ‘123 patent only suggests the removal of those glycoproteins that would cause an antigenic response, not that glycoproteins could not be added back to the composition. Applicant does not agree with the Examiner’s analysis. The ‘123 patent explicitly states that the fibrous tissue preparation is “free of nonfibrous tissue proteins and antigenic polysaccharides, mucopolysaccharides, and glycoproteins” (see the ‘123 patent: claims 1 and 3; col. 2, lines 9-16; and col. 4, lines 55-62). The ‘123 patent states that glycoproteins are antigenic and their removal is required to create a fibrous tissue composition that is suitable for implantation (see the ‘123 patent, col. 3, lines 33-59).

Furthermore, in column 3, lines 8-18, the ‘123 patent states that, even for transplants between individuals within a species, “such carbohydrate material may not be significantly antigenic, nevertheless it does not contribute to the strength of the tissue and may severely obstruct the subsequent recolonization of the graft by host cells, such as fibroblasts, and interfere with the formation of new capillaries within the graft.” Accordingly, the ‘123 patent teaches away from a graft composition comprising glycoproteins. Therefore, WO 98/25637 and the ‘123 patent cannot be combined because the ‘123 patent teaches away from combination with WO 98/25637. Moreover, the ‘123 patent expressly teaches away from Applicant’s claims 1-16 because the graft composition of Applicant’s claims “comprises a glycoprotein.”

In addition to the Examiner's arguments above regarding the '123 patent, the Examiner adds on pages 17-18 of the present Office Action, that "the teaching of Butler [WO 03/084410] further demonstrates that basement membrane was known in the prior art to be a suitable material for the repair of the body wall as well." In fact, WO 03/084410 also teaches away from the claimed invention. A skilled artisan would not rely on a reference that teaches that a support material in combination with a barrier material must be used to create a tissue composition that is suitable for body wall, to arrive at Applicant's amended claims which specify a graft composition *consisting essentially of basement membrane* for the repair of body wall tissue.

For example, it is stated on page 8, paragraph [0016] of WO 03/084410 that [t]he present invention demonstrates that integrating nondegradable structural support materials with biodegradable barrier materials reduces adhesions and increases well organized, cellular infiltration and neovascularization, resulting in thicker, healthier tissue development at the repair site.

Further, it is noted on page 8, paragraph [0017] of WO 03/084410 that

[t]he present invention pertains to compositions comprising at least one support material integrated with at least one biodegradable barrier material. Alternatively the composition can comprise two or more different biodegradable barrier materials, one of which can function as a support material.

Additionally, it is stated on page 13, paragraph [0031] of WO 03/084410 that

[t]he support material of the present invention can be comprised of any materials possessing the strength and structural integrity to promote the integrity of the wound or tissue closure.... The material is preferably permanent and non-biodegradable, particularly for load-bearing tissue, as absorbable materials lose tensile strength as they degrade and the resultant fibrous tissue does not have the strength to provide ongoing support for the repair.

Thus, WO 03/084410 teaches that a *nondegradable structural support material* combined with a *biodegradable barrier material* is needed to produce a graft with desirable characteristics, such as reduced adhesion formation, increased neovascularization,

healthier tissue development at the repair site, and increased strength. Furthermore, WO 03/084410 teaches that support materials that are permanent and non-biodegradable are preferred because absorbable materials lose tensile strength and are not suitable to provide ongoing support for the repair. Moreover, even though WO 03/084410 teaches that a barrier material (e.g., basement membrane) can function as a support material, WO 03/084410 indicates that ***two or more different biodegradable barrier materials*** are required. Therefore, WO 03/084410 expressly teaches away from Applicant's claims 1-16 because the graft composition ***consists essentially of basement membrane*** for the repair of body wall tissue.

Thus, contrary to the Examiner's contention, claims 1-16 of the instant application are not obvious over WO 98/25637 in view of the '110 patent, WO 03/084410, and the '123 patent. Withdrawal of the rejection of claims 1-16 under 35 U.S.C. § 103(a) is respectfully requested.

Rejection of Claims 1-16 For Obviousness-Type Double Patenting -

(1) The Examiner has rejected claims 1-16 as being unpatentable for obviousness-type double patenting over claim 11 of U.S. Patent No. 7,482,025 (hereinafter the '025 patent) in view of the '110 patent, WO 98/25637, WO 03/084410, and the '123 patent. Applicant respectfully traverses the Examiner's rejection.

Claim 11 of the '025 patent is directed to tissue grafts comprising gelled liver basement membrane and further comprising a component selected from the group consisting of a mineral, an amino acid, a sugar, a peptide, a protein, and a glycoprotein. Claim 11 does not require that DNA and endotoxins be removed from the graft composition. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Therefore, in order for Applicant's invention to be rendered unpatentable for obviousness-type double patenting, the combination of references relied upon by the Examiner must teach each and every element of Applicant's invention, as defined by claims 1-16. Applicant's claims 1-16 require the step of removing endotoxins from the graft composition. Because claim 11 of the '025 patent, WO 98/25637, the '110 patent, WO 03/084410, and the '123 patent do not provide any suggestion of the specific element of "removing endotoxins from the graft composition," the references either alone or when combined are incapable of defeating the patentability of Applicant's claims 1-16.

Furthermore, because the claims of the instant application require that the graft composition comprise a glycoprotein, the teaching away argument with respect to the '123 patent above applies with equal force to this obviousness-type double patenting rejection. Additionally, because the claims of the instant application require that the graft composition consists essentially of basement membrane of a warm-blooded vertebrate, the teaching away argument with respect to WO 03/084410 above applies with equal force to this obviousness-type double patenting rejection. Therefore, claims 1-16 are not obvious over claim 11 of the '025 patent in view of the '110 patent, WO 98/25637, WO 03/084410, and the '123 patent. Withdrawal of the rejection of claims 1-16 for obviousness-type double patenting is respectfully requested.

(2) The Examiner has rejected claims 1-16 as being unpatentable for obviousness-type double patenting over claims 1-3 and 9 of U.S. Patent No. 6,793,939 (hereinafter the '939 patent) in view of the '110 patent, WO 98/25637, WO 03/084410, and the '123 patent. The '939 patent is a continuation application of the U.S. national application that was based on the PCT application that published as WO 98/25637. Applicant respectfully traverses the Examiner's rejection.

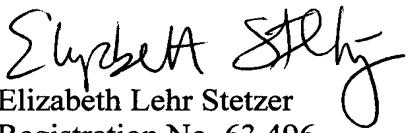
Claims 1-3 and 9 of the ‘939 patent are directed to tissue graft compositions comprising liver basement membrane wherein the basement membrane is devoid of endogenous cells. The claims do not require that DNA and endotoxins be removed from the graft composition. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Therefore, in order for Applicant’s invention to be rendered unpatentable for obviousness-type double patenting, the combination of references relied upon by the Examiner must teach each and every element of Applicant’s invention, as defined by claims 1-16. Applicant’s claims 1-16 require the step of removing endotoxins from the graft composition. Because claims 1-3 and 9 of the ‘939 patent, WO 98/25637, the ‘110 patent, WO 03/084410, and the ‘123 patent do not provide any suggestion of the specific element of “removing endotoxins from the graft composition,” the references either alone or when combined are incapable of defeating the patentability of Applicant’s claims 1-16.

Furthermore, because the claims of the instant application require that the graft composition comprise a glycoprotein, the teaching away argument with respect to the ‘123 patent above applies with equal force to this obviousness-type double patenting rejection. Additionally, because the claims of the instant application require that the graft composition consists essentially of basement membrane of a warm-blooded vertebrate, the teaching away argument with respect to WO 03/084410 above applies with equal force to this obviousness-type double patenting rejection. Therefore, claims 1-16 are not obvious over claims 1-3 and 9 of the ‘939 patent in view of the ‘110 patent, WO 98/25637, WO 03/084410, and the ‘123 patent. Withdrawal of the rejection of claims 1-16 for obviousness-type double patenting is respectfully requested.

CONCLUSION

The foregoing amendments and remarks are believed to fully respond to the Examiner's rejections. The claims are believed to be in condition for allowance. Applicant respectfully requests allowance of the claims, and passage of the application to issuance.

Respectfully submitted,


Elizabeth Lehr Stetzer
Registration No. 63,496

ELS/kat
Indianapolis, Indiana 46204
317-231-7228